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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/649,255	Applicant(s) DOMBROSKI ET AL.	
	Examiner Evelyn Huang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-17 are pending.

Election/Restrictions

2. In response to the restriction requirement mailed on 4-14-2004, Applicant has elected with traverse the Group I invention, claims 1-11. Group II, claims 12-17 are withdrawn as being drawn to the non-elected invention.

Applicant submits that the compounds of the invention are all MAP kinase inhibitors, preferably p38 kinase inhibitors. Since MAP kinase inhibitors can be used to treat arthritis, Alzheimer's disease and diabetes, as disclosed in the present application, these uses all relate to MAP kinase inhibitors and therefore, relate to the same invention. Accordingly, the MAP kinase inhibitors of the presently claimed invention are not being used in materially different processes. While Aricept can be used to treat Alzheimer's disease, Aricept is known to inhibit cholinesterase. Aricept is not a MAP kinase inhibitor. Therefore the process of using a compound that differs materially in structure from the claimed compounds has not been shown to be used as MAP kinase inhibitor.

On the contrary, the process of use claim is defined by the steps, which in the instant is administering the compound to the subject in need thereof, regardless of the mechanism(s) of action, such as inhibition of a MAP kinase. Accordingly, the presently claimed invention can be used in materially different processes in that it is administered to different subjects (those who suffer from arthritis, those who suffer from Alzheimer's disease and those who suffer from diabetes etc.). The instant process for treating Alzheimer's disease, can be practiced with a compound that differs materially in structure from the claimed compounds, such as Aricept. The restriction set forth in the previous office action is therefore proper.

Priority

3. This application claims the benefit of provisional application 60/407489. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Duplicate Claims

4. Claim 2 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being obvious over McClure (6696464).

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The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104; together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2). ***.

McClure generically discloses the instant anti-inflammatory compound (columns 89-90, claim 1; column 99, claim 15). A specific compound is disclosed (columns 71-2, Examples 3, 4; column 109, claim 50, lines 14-17).

McClure's Examples 3, 4 have a 4-fluoro-phenyl whereas the compound of instant claim 4, 5, or the first or last two compounds of instant claim 11, have a 2, 4- or 2, 5- difluoro-phenyl. McClure, however, teaches that the number and position of the fluoro substituents on the phenyl are optional choices (column 109, claim 49).

McClure's Examples 3, 4 have an unsubstituted cycloalkyl whereas the compound of instant claims 7-10 and the 2nd and 3rd compounds of instant claim 11 has a methyl substituted cycloalkyl. McClure, however, teaches that substituents on the cycloalkyl is optional (column 97, claim 5).

At the time of the invention, one of ordinary skill in the art would be motivated to modify the example compounds of McClure with the alternative optional substituents to arrive at the instant invention with the reasonable expectation of obtaining an additional anti-inflammatory compound since McClure had clearly taught that any species within the disclosed genus, especially the preferred subgenus, would be useful for the treatment of inflammatory diseases.

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Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 11 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 12 of copending Application No. 10/649236. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 15, 49, 50 of U.S. Patent No. 6696464.

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Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth in paragraph 5 above.

9. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-11 of copending Application No. 10/649236. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds are encompassed by the generic copending claims. The compounds of copending claims 4,5 is encompassed by the instant claims 1-5.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/649227 in view of McClure (6696464). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant compound has cycloalkyl whereas the copending compound has an alkyl as R2. However, McClure teaches that cycloalkyl and alkyl are optional choices for R2 (columns 96-7, claims 2-5). One of ordinary skill in the art would be motivated to replace the copending alkyl with the alternative cycloalkyl as taught by McClure to arrive at the instant invention with the reasonable expectation of obtaining an additional anti-inflammatory compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/649265 in view of McClure (6696464). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant compound has a difluorophenyl and a cycloalkyl as R2 whereas the copending compound has a trifluorophenyl and an alkyl as R2. However, McClure teaches that

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cycloalkyl and alkyl are optional choices for R2 (columns 96-7, claims 2-5) and phenyl may be substituted by 2 or 3 fluoro substituents (column 109, claim 49). One of ordinary skill in the art would be motivated to replace the copending tri-fluoro with the alternative difluoro and the copending alkyl with the alternative cycloalkyl as taught by McClure to arrive at the instant invention with the reasonable expectation of obtaining an additional anti-inflammatory compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/649216 in view of McClure (6696464). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant compound has a difluorophenyl whereas the copending compound has a trifluorophenyl. However, McClure teaches that the phenyl may be substituted by 2 or 3 fluoro substituents (column 109, claim 49). One of ordinary skill in the art would be motivated to replace the copending tri-fluorophenyl with the alternative difluorophenyl as taught by McClure to arrive at the instant invention with the reasonable expectation of obtaining an additional anti-inflammatory compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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